

the wound.

Further, the projections or barbs of Bays are not flexible. There is no suggestion or teaching in the Bays patent that the projections could be flexible. The disclosure in Bays
5 that the projection could be semi rigid does not suggest that they would be flexible. None of the Figures of Bays suggest any use of the Bays device that would permit the projections to be flexible.

The Bays device is held in place by the projections,
10 particularly the front projection which creates a hole in the tissue that is greater than the outside diameter of the remaining projections. The entire Bays rivet could retreat out of the opening after its insertion. The claims of the preset invention have been amended to recite that the projections are larger than
15 the largest diameter of the head. The projections do not increase the size of the opening in the tissue. As indicated in amended claim 9, the projections of the present invention are flexible, flexing as they are pushed through a smaller opening in the tissue than the largest outside dimensions of the
20 projections. This is not suggested or taught by Bays.

Further, there is no suggestion in Chisholm that the flexible projections of Chisholm could be incorporated in the Bays medical rivet device. The Bays device is a surgical rivet, designed for a very specific purpose. The Chisholm device is
25 for a standard rivet that would be used in conventional applications, such as in an automobile for holding cloth to plastic. There is no suggestion or teaching that the fastener of Chisholm could be used in a medical device to fasten tissue. The Bays patent specifically calls for rigid projections designed for
30 a specific purpose; namely meniscal repair. The Chisholm device is not relevant prior art.

Further, it would not be obvious to use projections that would not serve the purpose sought by Bays. The Bays projections are the same size as the dimension of the head, and
35 there is no suggestion that they be larger than the head.

Accordingly, it is believed that claim 9, as amended, presents novel and non obvious subject matter, and are allowable.

Referring to new claims 13 and 14, only three projections are shown in the Bays device. The first projection adjacent head 18 is designed to pass all the way through the tissue and the remaining two projections 16 hold the Bays rivet in place. However, no incremental positioning of the Bays rivet is possible. The projections of the Bays device require quantum placement. This results in the tissue being either not held closely enough together, or forced fitting of the tissue together. Neither condition is desirable.

The present invention of claims 13 and 14 provide for a dynamic rivet that resist the force of the tissue using the flexible projection to act as a spring to deal with changes in the relative position of the tissue to be held together. Also, new claim 13 recites that the projections are closely spaced next to one another along substantially the entire length of the shaft of the rivet so that the rivet can be pushed smoothly into the precisely desired position. No massive motion is required. Claim 14, dependent on claim 13, recites the existence of at least five (5) projections along the length of the shaft. The patent to Bays et al. does not include closely spaced projections, and the projections are not disclosed along substantially the entire length of the rivet.

New claims 13 and 14 are drawn dependent from claim 9 and are also believed to be allowable for the reasons set forth above, in the discussion of claim 9.

Claims 11 and 12 are drawn dependent on claim 9 and is behind allowable for the reasons set forth above. In addition, claims 11 and 12 have the driving means tip for a smooth transition from the tip of the driving means and the head of the rivet. The Examiner does not cite any portion of Bays that teaches or suggests such a feature in the rejection.

It is believed that all of the above claims, as amended, for the reasons set forth above, are all allowable and

that the application is in condition for allowance. Notice of Allowance is requested.

Should the Examiner have any further questions, please contact the undersigned directly.

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Respectfully submitted,



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